



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94732d

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

**WARNING LETTER**

**FLA-04-31**

May 11, 2004

Robert U. Craven, CEO  
Garden of Life Inc.  
5500 North Village Blvd.  
Suite 202  
West Palm Beach, Florida 33407-1901

Dear Mr. Craven:

From January 8 to January 23, 2004, the Food and Drug Administration inspected your firm at 1449 Jupiter Park Drive, Jupiter, Florida. During this inspection, the investigator collected copies of product labels, brochures, advertising materials, and other documents. Our review of these materials finds that your products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and implementing regulations on our Internet web site at [www.fda.gov](http://www.fda.gov).

**Products Labeled as Dietary Supplements**

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. We have reviewed labeling (including promotional materials) for a number of your products and have found the labeling to include disease claims that cause your products to be drugs as defined in section 201(g)(1)(B) of the Act. These claims include:

- **Ω-Zyme (OmegaZyme):**
  - Brochure:
    - Amylase – “Acts in association with lipase to digest fragments of viruses and reduce inflammation and infections.”
    - Lactase – “May be beneficial for those suffering from irritable bowel syndrome....”
    - Papain – “Used to treat chronic diarrhea and celiac disease. Treats gastrointestinal discomfort due to intestinal parasites.”
    - Poten-Zyme Cat’s Claw Extract – “Cat’s claw has been used ... as a treatment for ... urinary track infections and arthritis.”

- The product brochure also contains claims that imply that this product is useful for the treatment or prevention of numerous diseases, including colon cancer and arthritis.
- Primal Defense:
  - Trifold:
    - Testimonial: "[T]his product is the primary therapy I employ on a routine basis, especially as a treatment for patients suffering from inflammatory bowel disease."
    - Testimonial: "I am enthusiastic about Primal Defense as a treatment for Autism. ..."
    - "[B]een shown to drastically reduce populations of yeast, parasites and bad bacteria in the intestines."
- Fungal Defense:
  - Trifold:
    - "Powerful Anti-Candida Formula"
    - "Contains Potent Anti-Yeast and Anti-Fungal Compounds. . . [C]ertain conditions can cause fungi to multiply, weakening the immune system and causing infection. . . Fungal Defense delivers nature's most effective anti-yeast and anti-fungal compounds to actively help eliminate Candida from your body.. . Fungal Defense contains the most powerful anti-fungal substances found in nature. Wild Oregano and Olive Leaf Extracts are recognized for their potent anti-fungal, anti-bacterial, anti-viral, and anti-parasitic properties."
    - Taken together, statements in this document imply that the product will treat Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD). For example, the section titled, "What is Candida" states "[y]east overgrowth...is especially prevalent in hyperactive children and those with ADD and ADHD," and the section titled, "A Word on Diet" states that "[t]he powerful ingredients in Fungal Defense are specifically targeted to destroy yeast..."
- Extra Virgin Coconut Oil:
  - Trifold:
    - "Contains Antibacterial, Antiviral, Anti-fungal Properties"
    - "Helps to improve HDL and LDL Cholesterol Ratios"
    - "Coconut oil has been shown to ... help prevent bacterial, viral and fungal infections."
- Fruits of Life:
  - Product information sheet
    - "Research has shown that rheumatoid arthritis, chronic fatigue and even certain types of cancer are the direct result

of free radical damage. The destruction of healthy cells may be avoided by simply adding... Fruits of Life to your daily diet."

- Raisin: "contain ... a phytonutrient shown to have cancer-prevention effects." "Raisins are a rich sources of polyphenols and proanthocyanidins, which are recommended in prevention and treatment protocols for cardiovascular disease, cancer... asthma, diabetes, liver disease, cataracts, and macular degeneration."
  - Flavonoids: "Flavonoids contain antibacterial and antiviral properties...." "The flavonoids present in Fruits of Life ...strengthen and repair ... cardiac irregularities arising from a decrease in blood flow and arterial blockage."
  - Ellagic Acid: "Ellagic acid helps inhibit four different types of cancer causing agents..." "ellagic acid reduces the incidence of birth defects, promotes wound healing, reduces and reverses chemically induced liver fibrosis, and is helpful in the fight against heart disease."
  - Lists the following diseases and implies the product is useful in preventing or treating them: cancer, arteriosclerosis, high blood pressure, diabetes, arthritis, gout, kidney disease, chronic fatigue, osteoporosis, asthma, allergies, obesity, and tooth and gum diseases.
- FYI - For Your Inflammation:
    - Tri-fold:
      - "FYI consists of cartilage building proteins and mucopolysaccharides..., systemic enzymes, and specific whole foods and herbs . . . . These compounds contain powerful anti-bacterial and antiviral properties.."
      - Taken together, claims in this document imply that the product will treat disease such as arthritis. Examples of these claims include the following: "Components of FYI have been Clinically Proven to Reduce Effects of Inflammation;" and "Contains Herbs that may Inhibit the COX-2 Inflammation process."
    - Product information sheet
      - Lists the following disease claims and implies the product treats or prevents them: fibromyalgia, osteoarthritis, rheumatoid arthritis, bursitis, scleroderma, asthma, allergies, lupus, Chrons' and colitis.
      - Papain – "Papain is valuable as an anti-inflammatory agent as well as the ability to reduce the tissue irritation and joint inflammation in rheumatoid arthritis."

- Chicken Collagen Type II – “contains anti-inflammatory properties and has been clinically demonstrated to decrease pain and discomfort stemming from joint disorders.”
  - Poten-Zyme Cat’s Claw Extract – “has been extensively used to treat a wide range of illnesses including asthma, urinary tract inflammation, inflammatory bowel disease, arthritis, rheumatism....”
- RM-10:
  - Trifold:
    - “Potent Anti-Viral, Anti-Bacterial, and Anti-Fungal properties”
    - Testimonial: “It is effective in all degenerative autoimmune conditions”
    - “Surviving Cancer at 80”
  - Product catalog
    - Lists the following diseases and implies the product is useful in treating or preventing them: hepatitis, cancer, diabetes, AIDS, rheumatoid arthritis, Lupus
- RevivAll Classic:
  - Product information sheet
    - “Plant fats (phytosterols and sterolins) have been found to be effective in balancing immune response and useful in the treatment of autoimmune diseases like lupus and multiple sclerosis, as well as infectious diseases such as HIV, tuberculosis, and hepatitis C”
    - **“Malignancies:** Phytosterols and sterolins may block the development of tumors in the colon, breast, and prostate glands...”

In addition, the book, PATIENT Heal Thyself, references a number of diseases and states, “[T]ake these health supplements to alleviate symptoms and get well.” For example, your product, Primal Defense, is promoted for the treatment of autoimmune diseases such as Diabetes Type I, Grave’s Disease, Lupus, Multiple Sclerosis, Myasthenia Gravis, Rheumatoid Arthritis, and Scleroderma, and “Brain Health” diseases such as Alzheimer’s Disease and Parkinson’s. Your product, Zero Gravity, is promoted for the treatment of obesity and obesity-related diseases, such as cancer, diabetes, and heart disease. The book is considered labeling for your products, as it accompanies the products.

Based on the claims noted above, these products are drugs under the Act, since they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man [Section 201(g)(1)(B) of the Act]. Because the products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act. Under

section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)). The manufacturer of a dietary supplement containing a "structure/function" claim in the product's labeling must have substantiation that the claim is truthful and not misleading [21 U.S.C. § 343(r)(6)(B)].

### Medical Foods

During the inspection, the investigator also collected copies of labels for your products labeled as medical foods, RM-10 OM, Primal Defense OM, Perfect Food OM, and Living Multi OM. These products do not meet the definition of medical food in 21 USC 360ee(b)(3), which defines a medical food as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. The regulations further define a medical food as one that is intended for the dietary management of a patient who has special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the diet alone [21 CFR 101.9(j)(8)(ii)]. Your products RM-10 OM, Primal Defense OM, Perfect Food OM, and Living Multi OM are not medical foods because the product labels do not indicate that the products are intended for the specific dietary management of a disease or conditions for which distinctive nutritional requirements are established. Further, the diseases and conditions described in the product labeling do not have distinctive nutritional requirements and the products do not have any unique impact on the dietary management of those diseases and conditions beyond that which could be achieved by modification of the normal diet alone.

Because these products do not meet the definition of a medical food, they are not subject to the exemption from nutrition labeling afforded medical foods. Therefore, your products RM-10 OM, Primal Defense OM, Perfect Food OM, and Living Multi OM are misbranded within the meaning of section 403(q)(1) of the Act because the labels do not bear nutrition labeling in the appropriate format as prescribed in 21 CFR 101.9.

In addition, the labeling for the products RM-10 OM and FYI OM bears claims that indicate they are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease in man. Examples of these claims include the following:

- Original Medicine Wholefood Nutrition brochure:
  - RM-10 OM
    - “RM-10 OM....is known to improve the immunity of patients suffering from different conditions. An abnormally functioning immune system exposes you to many conditions such as; AIDS, Cancer, Allergies, M.S, Fibromyalgia, Diabetes, Syndrome X, Hepatitis, Rheumatoid Arthritis”
    - “Mushrooms and other foods have been used for centuries to defend against disease.”
  - FYI OM
    - “The following diseases, among others, produce inflammation: Alzheimers, Artherosclerosis, Cancer, Cardiovascular Disease, Osteoporosis, Arthritis, Stroke. FYI-OM's blend of foods has shown moderation of inflammation...”

These claims are evidence that the products are intended for use as drugs within the meaning of Section 201(g)(1)(B) of the Act. These products are new drugs under section 201(p) of the Act because there is no evidence that these products are generally recognized as safe and effective for their intended uses. Therefore, they may not be legally marketed in the United States without approved new drug applications (section 505 of the Act).

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm and all labeling for such products comply with the Act and its implementing regulations. Labeling may include your websites [www.gardenoflifeusa.com](http://www.gardenoflifeusa.com) and [www.silverspringsupplements.com](http://www.silverspringsupplements.com) , flyers, trifold, product catalogs, books promoting your products, compact disks, training materials, and other sources.

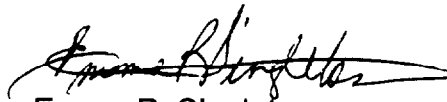
The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

We note that in your January 30, 2004 letter to Ms. Susan Corrales, you indicated that the medical food products are no longer being sold; however, they are still shown on your Internet web site. In addition, your letter states that the product materials are being revised and that the book PATIENT Heal Thyself will no longer be made available. Please provide the final version of any product brochures or accompanying materials that will be used.

Your reply should be addressed to Shari H. Shambaugh, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton  
Director, Florida District

cc: Jordan S. Rubin, Chairman  
Garden of Life Inc.  
770 Northpoint Parkway, Suite 100  
West Palm Beach, Florida 33409